

## Technical Data Sheet (TDS)

**Lithium Carbonate CAS:554-13-2 Version Date: 28 FEB 2026**

### 1. Product Overview

- Product Name: Lithium Carbonate (碳酸锂)
- CAS Number: 554-13-2
- Formula:  $\text{Li}_2\text{CO}_3$
- Molecular Weight: 73.89 g/mol
- Chemical Classification: Inorganic lithium salt
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for bipolar disorder/anti-manic drugs; mild hygroscopy; sparingly soluble in water; stable under controlled storage; strict heavy metal/impurity limits for pharmaceutical use.

### 2. Technical Specifications (EP 10.0 / USP 45 / CP 2020)

Item	Specification	Test Method
Appearance	White crystalline powder/granules	Visual Inspection
Assay (on dry basis)	$\geq 99.0\%$	Acid-Base Volumetric Titration
Loss on Drying	$\leq 0.5\%$	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	550°C Ignition Method
Heavy Metals (Pb)	$\leq 5$ ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride Content	$\leq 0.01\%$	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	Volumetric Titration
Iron Salt (Fe)	$\leq 0.001\%$	Colorimetric Method
Calcium Salt (Ca)	$\leq 0.02\%$	AAS
Magnesium Salt (Mg)	$\leq 0.005\%$	AAS
pH Value (1% aq. suspension, 25°C)	6.0-8.0	Digital pH Meter
Solubility	Sparingly soluble in water, insoluble in ethanol	Pharmacopoeial Solubility Test
Particle Size	90% passing 100 mesh	Sieve Analysis

### 3. Product Advantages

1. **Pharmacopoeial Compliance:** Meets EP/USP/CP international standards; ultra-low heavy metal/impurity content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation.
2. **Potent Therapeutic Effect:** Gold standard API for bipolar disorder (manic-depressive psychosis); effective for acute mania and maintenance treatment; stable blood concentration when formulated properly.
3. **High Purity & Safety:** Pharmaceutical grade with  $\geq 99.0\%$  assay; strict control of toxic impurities (Pb/As/Fe); minimal side effects at clinical therapeutic doses.
4. **Stable Quality:** 24-month shelf life under dry storage; mild hygroscopy (controllable with sealed packaging); no chemical degradation under normal pharmaceutical processing.



## NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

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5. **GMP Manufacturing:** Produced in GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process quality control for all parameters.

### 4. Application Fields

- **Pharmaceutical Formulation:** Production of anti-manic/bipolar disorder drugs (tablets, capsules, sustained-release formulations) for clinical treatment of manic episodes and mood stabilization.
- **Industrial Use:** Small-scale additive for ceramic/glass manufacturing (improves hardness/transparency); lithium ion battery raw material (industrial grade only).
- **R&D Application:** Pharmaceutical research on new lithium salt formulations; neuroscience research on bipolar disorder pathogenesis; inorganic material development (industrial grade).

### 5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for solid oral dosage forms (tablets/capsules/sustained-release pellets); compatible with common excipients (microcrystalline cellulose, lactose, starch); avoid formulation with strong acids.
- **Typical Dosage (Formulated Drug):** Adult oral dosage 0.75-1.5 g/day (divided doses); **therapeutic drug monitoring (TDM) required** to maintain blood lithium 0.8-1.2 mmol/L (clinical prescription only).
- **Processing Precautions:** Process in dust-free, low-humidity (<60%) GMP workshop; use closed handling systems to avoid dust inhalation/hygroscopy; avoid contact with strong acids (releases CO<sub>2</sub>).

### 6. Packaging & Storage

#### 6.1 Packaging Specifications

- 100 g/bottle (HDPE bottle with aluminum foil moisture-proof seal, inner plastic liner)
- 500 g/bottle (HDPE bottle with moisture-proof seal)
- 1 kg/drum (sealed HDPE drum with inner plastic bag)
- 5 kg/drum (fiber drum with HDPE inner liner, moisture-proof)
- Custom GMP-compliant packaging for industrial bulk orders

#### 6.2 Storage Conditions

- Store in a **cool, dry, well-ventilated warehouse** at ≤25°C; keep container tightly sealed to prevent hygroscopy and caking; avoid high humidity (>60%) and direct sunlight.
- Incompatibilities: Store separately from strong acids, strong oxidizing agents, acidic salts and food/feed materials.
- Shelf Life: **24 months** (unopened, specified conditions); 6 months after opening (resealed, dry storage).

#### 6.3 Transportation

- Classified as UN 3288 (Class 9 Miscellaneous Hazardous Material); transport with moisture-proof sealed packaging; maintain temperature ≤25°C.
- Mark with GHS hazard labels and UN 3288; avoid collision/vibration and contact with strong acids during transport; comply with IMDG/IATA/ADR for Class 9 goods.

### 7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility; strict in-process quality control for all key parameters (assay, heavy metals, impurities).
- Each batch is accompanied by a batch-specific **Certificate of Analysis (COA)** with full test results; quality records retained for 5 years (per GMP requirements).
- Complete raw material traceability system; professional technical support for pharmaceutical formulation development and process optimization.